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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,836	08/16/2001	Luc Desnoyers	P3030R1C1	5218

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GENENTECH, INC.
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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

JIANG, DONG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,836

Applicant(s)

DESNOYERS ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is **non-final**.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED OFFICE ACTION

Applicant's amendment filed on 24 November 2003 is acknowledged and entered. Following the amendment, claim 23 is amended, and claims 27-29 and 32 are canceled.

Currently, claims 22-26, 33 and 34 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 27-29 and 32 are moot as the applicant has canceled the claims.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22-26, 33 and 34 remain rejected under 35 U.S.C. 102(e) as being anticipated by Piddington et al., US 6,521,233 B1, for the reasons of record set forth in the last Office Action, paper No. 12, mailed on 20 August 2003, at page 2.

Applicants argument filed on 24 November 2003 has been fully considered, but is not deemed persuasive for reasons below.

At pages 5-6 of the response, the applicant argues that Piddington does not anticipate the present claims because Piddington fails to enable one of skill in the art to make and use the claimed invention, and that a claim can only be anticipated by a reference if the publication describes the claimed invention with sufficient enabling detail to place the public in possession of the invention, according to the case laws cited by applicants. This argument is not persuasive because Piddington teaches the polypeptide sequence of human zacrp3, which sequence is 100% identical to SEQ ID NO:2 of the instant invention. As such, Piddington's description of the amino acid sequence clearly provides sufficient enabling detail to place the public in possession

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of the invention, as any one of skill in the art would be able to make the polypeptide based on the amino acid sequence taught by Piddington. Further, in *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, 346 F.3d 1051 (Fed. Cir. 2003), cited by applicants, it is said that “enablement requires that ‘the prior art reference must teach one of ordinary skill in the art to make *or* carry out the claimed invention without undue experimentation’”. The Piddington reference meets such an enablement requirement as it teaches how to make the polypeptide. With respect to the requirement that the anticipating reference must enable to make *and use* the claimed invention, the Examiner is not able to locate such recitation in the case law cited by applicants. Further, the statute of 102(e) itself merely requires that “the invention was *described* in ...”. The present invention is directed to a product, an isolated polypeptide, which sequence was disclosed in the prior art reference. As such, the polypeptide of the present invention has been well described by the prior art reference, and the prior art reference meets the anticipating requirement of 102(e).

At page 6 of the response, the applicant further argues that the Piddington provisional application (filed on April 20, 1999) fails to teach how to make and use invention of the present claims without undue experimentation as the present claims recite isolated polypeptide variants having ability to induce chondrocyte redifferentiation, and the Piddington provisional application does not recognize such ability of the polypeptides. This argument is not persuasive because the Piddington provisional application teaches the amino acid sequence of the polypeptide, which meets the limitation of “at least 80% (or 85, 90, 95, 99%)” in the present claims. The present claims, as written, encompass the polypeptide that is 100% identical to SEQ ID NO:2. Further, the disclosed amino acid sequence enables one of skill in the art to make the claimed invention. With respect to the functional limitation, the ability to induce chondrocyte redifferentiation is inherent because the presently claimed polypeptide SEQ ID NO:2 is 100% identical to that of the prior art. According to MPEP, “when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent”, and “if the composition is physically the same, it must have the same properties” (see MPEP 2112.01). The present invention is directed to a product, an isolated polypeptide having the same amino acid sequence as that of the prior art. Although Piddington did not recognize the presently recited property, the newly discovered property of a known product is inherent. As such, the

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newly discovered property of the polypeptide to induce chondrocyte redifferentiation does not render the instant claims novel, and they are not patentable over the prior art.

Conclusion:

No claim is allowed.

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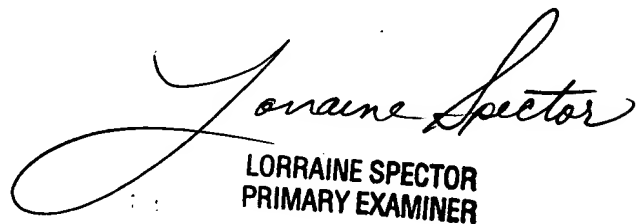
Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
2/16/04